Exhibit 6 – *In re Nat'l Prescr. Opiate Litig.*, No. 1:17-md-2804 (N.D. Ohio Aug. 6, 2020) (Doc. 3403)

Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Plaintiff Cabell County Commission's Right to Abatement

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL 2804**
	)	**Case No. 1:17-MD-2804**
THIS DOCUMENT RELATES TO:	)	**Judge Dan Aaron Polster**
Track Three Cases:	)	**OPINION AND ORDER**
County of Lake, Ohio v. Purdue Pharma, L.P., et al., Case No. 18-OP-45032	)	
County of Trumbull, Ohio v. Purdue Pharma, L.P., et al., Case No. 18-OP-45079	)	

Before the Court is the Pharmacy Defendants'[1] Motion to Dismiss Second Amended Complaints. Doc. #: 3340.[2] Plaintiffs (Ohio's Lake and Trumbull Counties) filed an opposition brief. Doc. #: 3366. Pharmacy Defendants filed a reply brief. Doc. #: 3379. For the reasons stated below, the Motion to Dismiss is **DENIED**.

[1] The Motion was filed collectively by the following defendant families: (1) Walmart Inc., Wal-Mart Stores East, LP, WSE Management, LLC, WSE Investment LLC, and Wal-Mart Stores East, Inc. (collectively, "Walmart"); (2) CVS Health Corporation, CVS Pharmacy, Inc., CVS Indiana, L.L.C., CVS Rx Services, Inc., CVS TN Distribution, L.L.C., and Ohio CVS Stores L.L.C. (collectively, "CVS"); (3) Rite Aid Hdqtrs. Corp., Rite Aid of Ohio, Inc., Rite Aid of Maryland, Inc., and Eckerd Corp. d/b/a Rite Aid Liverpool Distribution Center (collectively, "Rite Aid"); (4) Walgreen Boots Alliance, Inc., Walgreen Co., and Walgreen Eastern Co. (collectively, "Walgreens"); and Giant Eagle, Inc., and HBC Service Company (collectively, "Giant Eagle"). The Court refers to all of these entities collectively as "Pharmacies" or "Pharmacy Defendants."

[2] Unless otherwise indicated, all document numbers refer to the MDL docket, Case No. 17-MD-2804. Page numbers refer to the documents' native format pagination. The amended complaints are filed at Doc. ##: 3326 & 3327.

I. Legal Standard.

The Court incorporates by reference the applicable legal standards set forth in its *Opinion and Order in Cleveland Bakers & Teamsters Health & Welfare Fund v. Purdue Pharma, L.P.*, Case No. 1:18-OP-45432 (Doc. #: 3177 at 4–6).[3]

II. Factual Allegations.

Plaintiffs each assert a claim of common law absolute public nuisance against the Pharmacy Defendants.[4] This Opinion addresses the viability of the public nuisance claims as they arise out of Pharmacy Defendants' activity of *dispensing* prescription opioids to customers. The Court previously concluded under Ohio law that nearly identical claims based on the Pharmacy Defendants' *distribution* activity survive a motion to dismiss. *See Opinion and Order in The County of Summit, Ohio v. Purdue Pharma L.P.*, Case No. 18-OP-45090 (Doc. #: 1203).[5]

With respect to dispensing practices, Plaintiffs contend the Pharmacy Defendants violated the Federal Controlled Substances Act and also Ohio controlled substance laws by, among other things, "dispensing and selling [opioids] without maintaining effective controls against the diversion of opioids." *Amended Complaint*, Doc. #: 3327 at ¶630(b).[6] In particular, Plaintiffs allege the Pharmacy Defendants failed to: "adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers," *id.* at ¶82; "put in place effective policies and procedures to prevent their stores from facilitating

[3] *In re Nat'l Prescription Opiate Litig.*, 440 F. Supp. 3d 773, 783-84 (N.D. Ohio 2020).

[4] The Motion and this Opinion and Order address only Plaintiffs' public nuisance claims against the Pharmacy Defendants (Count XI). Pursuant to this Court's Order, Doc. #: 3315, Plaintiffs' other claims against the Pharmacy Defendants and all claims against other defendants are stayed for later discovery and trial.

[5] *In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898 (N.D. Ohio Dec. 19, 2018).

[6] Because the Plaintiffs' Amended Complaints are nearly identical, the Court, like the parties, cites to Lake County's Amended Complaint for ease of reference.

diversion and selling into a black market," *id.* at ¶83; "conduct adequate internal or external reviews of their opioid sales to identify patterns regarding prescriptions that should not have been filled," *id.*; "effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions," *id.* at ¶85; and "take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances," *id.* at ¶86. Plaintiffs further allege the Pharmacies "had the ability, and the obligation, to look for [] red flags on a patient, prescriber, and store level, and to refuse to fill and to report prescriptions that suggested potential diversion," *id.* at ¶541, but the Pharmacy Defendants "systemically ignored red flags that they were fueling a black market." *Id.* at ¶81. Plaintiffs allege the result of all this conduct is that the Pharmacy Defendants distributed and dispensed opioids "in a manner which caused prescriptions and sales of opioids to skyrocket in Plaintiff's community, flooded Plaintiff's community with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market." *Id.* at ¶621.

III. Analysis.

The Pharmacy Defendants argue there are four reasons why federal and Ohio law require dismissal of Plaintiffs' public nuisance claims based on dispensing activity. The Court considers each argument in turn.

A. Statutory Abrogation of Plaintiffs' Public Nuisance Claims.

The Pharmacy Defendants begin their motion with the contention that Ohio statutes (and associated regulations) that govern "distribution of a drug of abuse" displace the common law and thereby entirely preclude Plaintiffs' absolute public nuisance claims. Defendants explain that the

"Ohio legislature has comprehensively regulated the field of controlled substance dispensing and distribution, and has provided specific remedies that conflict with any common law cause of action." Doc. #: 3340-1 at 1. Defendants insist the Plaintiff Counties "can bring their claim under the appropriate statute, Ohio Rev. Code ("O.R.C.") § 4729.35, or not at all." *Id*. at 7. The Court finds this position unpersuasive.

The statute at issue falls under Title 47 of the Revised Code, "Occupations–Professions," which establishes professional standards applicable to 66 different occupations. Chapter 4729, titled "Pharmacists; Dangerous Drugs," governs numerous matters related to the practice of pharmacy, including: licensing; required and prohibited conduct; distribution and dispensing of prescription medication; and disciplinary actions against pharmacies and pharmacists.[7] The Chapter also establishes a State Board of Pharmacy ("OBOP") to administer and enforce the provisions of the Chapter, and to adopt rules to carry out its purposes. O.R.C. §§ 4729.01–4729.99; *see, e.g., Ohio State Bd. of Pharm. v. Dick's Pharmacy*, 780 N.E.2d 1075, 1077-82 (Ohio Ct. App. 2002) (affirming OBOP's imposition of a $25,000 civil fine against a pharmacy based on its determination that the pharmacy and its pharmacist-in-charge engaged in illegal dispensing of dangerous drugs).

Under the OBOP's rules, "[a]ll licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs." Ohio

[7] *See, e.g.*, O.R.C. §§ 4729.07 (licensing application and examination); 4729.071 (criminal records check); 4729.08 (qualifications); 4729.28 (unlawful selling of drugs or practice of pharmacy); 4729.35 (unlawful distribution of drugs of abuse; prosecution); 4729.37 (record keeping); 4729.46 (limitations on dispensing opioid analgesics); 4729.01(Q) ("'terminal distributor' includes pharmacies … who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist"); 4729.77 (terminal distributor pharmacies to submit prescription information); 4729.80 (submission of database information); 4729.281 (dispensing of drug without written or oral prescription); 4729.292 (annual on-site inspection of opioid treatment program).

Admin. Code §§ 4729-9-05(A), 4729-9-11, 4720-9-16(H).[8] Section 35 of Chapter 4729 declares violations of federal or state laws and regulations governing the distribution and dispensing of opioids to constitute a public nuisance *per se*.[9] It authorizes the attorney general, county prosecutors, and the OBOP to maintain a civil action "in the name of the state" to enjoin violative conduct. An injunction is the only remedy available under that section.[10]

Plaintiffs, however, do not assert a cause of action under O.R.C. § 4729.35. Rather, they bring *common law* absolute public nuisance claims, alleging that Defendants' violations of anti-diversion laws gave rise to a public nuisance. Doc. #: 3327 at ¶¶71-599, 616-654.

The Pharmacy Defendants insist Ohio law allows only the statutory public nuisance claim provided for in O.R.C. § 4729.35, so Plaintiffs' common law public nuisance claims must be dismissed. In support, Defendants rely on: (1) rules of statutory construction, (2) the doctrine of field preemption, and (3) assertions of irreconcilable conflict. Each topic is addressed below.

1. Rules of Construction Regarding Abrogation.

The Ohio Supreme Court has consistently recognized the following rule of statutory construction:

> Statutes are to be read and construed in the light of and with reference to the rules and principles of the common law in force at the time of their enactment,

[8] Sections 4729-9-05(A) and 4729-9-16(H) of the Code were recently rescinded, revised, and reorganized. The provisions of the Code cited above presently appear at §§ 4729:5-3-14 and 4729:6-3-05.

[9] O.R.C. §§ 3719.01(C) & 3719.011(A) define "opiate" as "a drug of abuse."

[10] O.R.C. § 4729.35 provides:

> The violation by a pharmacist or other person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse as defined in section 3719.011 of the Revised Code or the commission of any act set forth in division (A) of section 4729.16 of the Revised Code, is hereby declared to be inimical, harmful, and adverse to the public welfare of the citizens of Ohio and to constitute a public nuisance. The attorney general, the prosecuting attorney of any county in which the offense was committed or in which the person committing the offense resides, or the state board of pharmacy may maintain an action in the name of the state to enjoin such person from engaging in such violation.

> and in giving construction to a statute the Legislature will not be presumed or held to have intended a repeal of the settled rules of the common law, ***unless the language employed by it clearly expresses or imports such intention***.

State ex rel. Morris v. Sullivan, 90 N.E. 146, syllabus ¶ 3 (Ohio 1909) (emphasis added). Put more succinctly, an intent to abrogate the common law "must be expressly declared by the legislature or necessarily implied in the language of the statute." *LaCourse v. Fleitz*, 503 N.E.2d 159, 161-62 (Ohio 1986) (citation omitted)*; see also Combs v. Ohio Dep't of Nat. Res., Div. of Parks & Recreation*, 55 N.E.3d 1073, 1078 (Ohio 2016) ("in the absence of language clearly showing the intention to supersede the common law, the existing common law is not affected by the statute, but continues in full force") (internal quotation marks and citations omitted).[11]

As Plaintiffs note, § 4729.35 does not expressly abrogate any common law or equitable cause of action or remedy (and neither does any other section of Chapter 4729). Despite this, Defendants contend there is an exception to the *Morris* statutory construction rule: it "applies only to the repeal of '***settled*** rules of the common law.'" Doc. #: 3379 at 2 (emphasis added). Defendants argue that "diversion of controlled substances" had no meaning at common law, so the General Assembly had no reason to declare the common law was abrogated. Put differently, Defendants assert that common law public nuisance claims asserting diversion of controlled substances "never existed in the first place," *id*. at 2-3, so there was no need for § 4729.35 to include "language clearly showing the intention to supersede th[is] common law." *Combs*, 55 N.E.3d at 1078.

Defendants' theory, however, constrains the *Morris* rule of construction to an unsupportable level of specificity. Defendants ignore that Ohio courts for many decades have recognized a common law claim for absolute public nuisance based on a defendant's unlawful

[11] *See also Frantz v. Maher*, 155 N.E.2d 471, 476 (Ohio Ct. App. 1957) ("An intention of the General Assembly to abrogate common-law rules must be manifested by express language. There is no repeal of the common law by mere implication."); *In re Nicole Gas Prod.,* 581 B.R. 843, 850 (B.A.P. 6th Cir. 2018) (citing *Morris* and applying the same rule).

conduct. *See, e.g., Taylor v. Cincinnati*, 55 N.E.2d 724, 727-32 (Ohio 1944). Undoubtedly, the General Assembly was aware of the *Morris* rule of construction when it enacted § 4729.35 and could easily have abrogated some or all of the existing species of common law public nuisance claims, whether premised upon diversion of controlled substances or any other intentional, unlawful, or hazardous conduct. Indeed, the General Assembly has abrogated very specific types of common law claims in other statutes, as well as entire categories of common law claims. *See, e.g.,* O.R.C. § 2307.98(E) ("This [shareholder liability] section is intended to codify the elements of the common law cause of action for piercing the corporate veil and to *abrogate the common law cause of action and remedies relating to piercing the corporate veil in asbestos claims.*"); O.R.C. § 2307.71(b) (stating that certain provisions in the Revised Code "are intended to *abrogate all common law product liability claims or causes of action*"). The fact that the Legislature did not do so in § 4729.35 negates any presumption that it intended to abrogate any aspect of the common law. *Morris,* 90 N.E. 146, syllabus ¶ 3.

Ohio case law further supports the conclusion that the Ohio Legislature did not intend to abrogate common law public nuisance claims or remedies when it enacted § 4729.35. Ohio courts have repeatedly held that § 3767.03, a general nuisance statute, does not supersede or preempt common law public nuisance claims. *See, e.g., Pizza v. Sunset Fireworks Co.,* 494 N.E.2d 1115, 1120 (Ohio 1986) ("[T]he appellate court concluded that the existence of R.C. 3767.03 in no way limited the right of a prosecutor to initiate an injunctive action in the case of a common law nuisance. We agree with the appellate court."); *Christensen v. Hilltop Sportsman Club, Inc.*, 573 N.E.2d 1183, 1184-85 (Ohio Ct. App. 1990) ("Although R.C. Chapter 3767 provides a statutory basis for nuisance actions, we do not accept appellant's argument that the statute supersedes all common-law nuisance. There is no language within the statute that provides that it was the

legislature's intent to supersede common-law nuisance and no court in Ohio has so held."); *Haas v. Sunset Ramblers Motorcycle Club, Inc.*, 726 N.E.2d 612, 614-15 (Ohio Ct. App. 1999) ("Although R.C. 3767.03 provides that a private citizen, as well as certain enumerated public officials, has the right to bring an action in equity to request a court to abate a presumably public nuisance and to enjoin the defendant from further maintenance of such nuisance, there is no language in the statute that provides that it was the legislature's intent to supersede common-law nuisance."); *Winkelmann v. Cekada*, 738 N.E.2d 397, 399-400 (Ohio Ct. App. 1999) ("In addition, the common-law tort of private nuisance survived the enactment of R.C. Chapter 3767."). These cases all stand for the proposition that common-law nuisance claims should not be deemed superseded by statute, absent clear language that says so.

2. Comprehensive Legislation.

Using an argument analogous to field preemption, Defendants also assert the specificity and comprehensive nature of Ohio's regulatory scheme governing distribution and dispensing of controlled substances implies an intent by the General Assembly to displace the common law and "limit[] public nuisance liability to the [injunctive] relief permitted under Section 4927.35." Doc. ##: 3340-1 at 8-13; 3379 at 3-4. Defendants cite *Thompson v. Ford* for the proposition that common law is superseded when the General Assembly enacts "general and comprehensive legislation, prescribing minutely a course of conduct to be pursued, the parties and things affected, and elaborately describing limitations and exceptions." 128 N.E.2d 111, 115-16 (Ohio 1955) (quoting 3 Sutherland Statutory Construction § 5305 (3d ed.)). *Thompson*, however, did not hold that the comprehensive nature of a statute necessarily implies legislative intent to displace all common law causes of action. Rather, as Plaintiffs correctly assert, *Thompson* merely concluded the statutory negligence *standard of care* displaced the common law negligence *standard of care*.

Doc. #: 3366 at 8. Nothing in the decision indicates an intent by the General Assembly that comprehensive statutory language should work to abolish common law *causes of action* or available remedies.

Defendants also assert Ohio's statutory scheme governing dangerous drugs is analogous to the federal scheme, set out in the Controlled Substances Act ("CSA"), "that balances the competing public health goals of making medications available to patients who need them and controlling against their abuse." Doc. #: 3340-1 at 12-13 (quoting *Gonzales v. Raich*, 545 U.S. 1, 24 (2005)). Nothing in *Gonzales*, however, supports Defendants' contention that, as a matter of law, Ohio's statutory scheme precludes a common law public nuisance claim based on conduct the statute proscribes.[12] To the contrary, this Court previously held that, even though the distribution of controlled substances is regulated under a comprehensive federal scheme, a claim under Ohio common law for absolute nuisance is not foreclosed. *See In re Nat'l Prescription Opiate Litig.*, 440 F. Supp. 3d at 808 (Doc. #: 3177 at 45) (rejecting the Distributor Defendants' contention that "they are not subject to nuisance liability because their business activities are authorized and extensively regulated by state and federal law").

3. Codification of the Common law and Irreconcilable Conflict.

Defendants next offer the related argument that the Plaintiffs' common law public nuisance claims are precluded because the Ohio legislature has "codified" the law governing distribution and dispensing of controlled substances, and has not demonstrated an intent for the statutory

[12] In *Gonzales*, the United States Supreme Court found that applying the CSA's criminal provisions regarding the manufacture, distribution, or possession of marijuana to California's in-state growers and medical marijuana users did not violate the Commerce Clause. *Gonzales,* 545 U.S. at 24-33. In reaching this conclusion, the *Gonzales* court noted the CSA creates a "comprehensive framework for regulating the production, distribution, and possession of 'controlled substances,'" most of which "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." *Id.* at 24.

provisions to be "cumulative" to common law. Doc. #: 3340-1 at 7-8. Under Ohio law, where the General Assembly has codified the law on a subject, "unless there is a clear legislative intention expressed or necessarily implied that the statutory provisions are merely cumulative," the statutory provisions govern to the exclusion of prior non-statutory law. *Metz v. Unizan Bank*, 2006 WL 8427066, at *10 (N.D. Ohio Feb. 28, 2006) (citing *Bolles v. Toledo Trust Co.*, 58 N.E.2d 381, syllabus ¶ 13 (Ohio 1944)).

Defendants attempt to support their position with cases involving claims arising under the Uniform Commercial Code ("UCC"). *See* Doc. #: 3340-1 at 7-8, 12-13 (citing *Alotech, Ltd. v. Huntington Nat'l Bank*, 2014 WL 281973, at *3-4 (N.D. Ohio Jan. 24, 2014); *Amzee Corp. v. Comerica Bank-Midwest*, 2002 WL 1012998, at *1 (Ohio Ct. App. May 21, 2002); *Peters Family Farm, Inc. v. Sav. Bank*, 2011 WL 497476, at *3 (Ohio Ct. App. Jan. 28, 2011); and *Baggott v. Piper Aircraft Corp.*, 101 F. Supp.2d 556, 561 (S.D. Ohio 1999)). These cases, however, are all readily distinguishable.

Unlike Chapter 4729 (which, as discussed above, governs the State's licensing, regulatory, and enforcement powers regarding pharmacies and does not address claims or remedies available to parties at common law), the UCC clearly codifies the law governing commercial transactions between private parties, including remedies. *See, e.g.*, *Metz,* 2006 WL 8427066, at *11 (UCC § 1-103 expresses the Ohio legislature's intent to: (1) "simplify, clarify, and modernize the law governing commercial transactions;" (2) "permit the continued expansion of commercial practices through custom, usage, and agreement of the parties;" and (3) "make uniform the law among various jurisdictions"); *Baggott*, 101 F. Supp.2d at 561 ("UCC § 2-607(5) is a codification of common law voucher in the context of the sale of goods"). Moreover, the UCC itself expressly provides that its provisions displace some—but not all—common law claims. *See Metz*, 2006

WL 8427066, at *10 (under UCC § 1-103, unless displaced by the UCC's particular provisions, the principals of law and equity shall supplement the UCC's provisions); *Alotech*, 2014 WL 281973, at *3 ("The UCC does not purport to codify the entire body of law affecting the rights and obligations of parties to commercial transactions.").

In the UCC cases cited by Defendants, the courts held that, where the UCC governs the particular conduct at issue, a plaintiff cannot assert a *conflicting* common law claim to circumvent the liabilities, responsibilities, and remedies provided under the UCC.[13] Defendants have not shown that allowing the Plaintiffs' public nuisance claims to proceed would in any way conflict or interfere with an authorized entity's ability to enjoin the same alleged unlawful conduct under § 4729.35. Nor have they demonstrated § 4729.35 is a codification of the common law.

Defendants also cite an Ohio rule of statutory construction, O.R.C. § 1.51,[14] which provides that "special or local" provisions control over irreconcilable general provisions – a rule this Court applied in its Track One Order addressing Plaintiffs' statutory nuisance claims. Doc. :# 3340-1 at 13 (citing *In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at *17 (Doc. #: 1203 at 30)). Defendants write: "Much as this Court concluded that the specific provision, Section 4729.35, must control over an irreconcilable general [public nuisance] statute, this same provision must prevail over an irreconcilable common law cause of action." *Id.* But the Track One Order addressed

[13] *See Peters Family Farm*, 2011 WL 497476, at *3-4; *Alotech,* 2014 WL 281973, at *4 (the UCC's statutory duty of care displaced the common law's duty of ordinary care; thus, plaintiff's exclusive remedy for its negligence claim was under the UCC); *Amzee*, 2002 WL 1012998, at *9-10 (the UCC provides different liabilities and responsibilities for negotiable instruments than those existing at common law and therefore supplants common law claims based on conduct governed by the UCC).

[14] *See* O.R.C. § 1.51 ("If a general provision conflicts with a special or local provision, they shall be construed, if possible, so that effect is given to both. If the conflict between the provisions is irreconcilable, the special or local provision prevails as an exception to the general provision, unless the general provision is the later adoption and the manifest intent is that the general provision prevail.").

a conflict between statutory causes of action and did not address an alleged conflict between statutory and common law claims.[15]

The fact that § 4729.35 provides authorized persons with a statutory public nuisance claim to enjoin unlawful conduct does not demonstrate an intent to preclude those or other persons from also obtaining relief at common law for harm caused by the same wrongful conduct. In fact, in Track One, the Court found the City of Akron lacked standing to bring a *statutory* public nuisance claim under § 4729.35, *see* Doc. #: 1203 at 30-31, yet also found the City stated a *common law* public nuisance claim under Ohio law, *see id.* at 23-28 (finding the Ohio Products Liability Act did not abrogate plaintiffs' common law absolute nuisance claims). Defendants point to no facts or authority demonstrating an irreconcilable conflict between a claim brought by a county under § 4729.35 and a common law public nuisance claim.

4. Conclusion.

Under the approach urged by Defendants, pharmacists, pharmacies, and "other person[s]"[16] who violate a state or federal law or regulation governing controlled substances would be subject only to an order enjoining the misconduct. This reading would immunize an entity from common law liability for the consequences of this conduct, even if it causes a dire nuisance by unreasonably interfering with the public's right to health and safety. To find the General Assembly intended this

[15] The Track One Plaintiffs asserted a statutory public nuisance claim under (i) O.R.C. § 4729.35 and also (ii) general sections O.R.C. §§ 715.44(A) (authorizing municipalities to "abate any nuisance") and 3767.03 (Ohio's general nuisance provision). Section 3767.03 confers standing on a broader range of persons than § 4729.35 and provides abatement ***and*** injunctive remedies. After finding the special Section was irreconcilable with the general Sections, the Court concluded the provisions of § 4729.35 prevailed to limit the categories of relief and parties with standing to sue. Doc. #: 1203 at 28-31 (citing *United Tel. Co., v. Limbach*, 643 N.E.2d 1129 (Ohio 1994)).

[16] Chapter 4729 defines "Person" as including "any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions." O.R.C. § 4729.01(S).

outcome strains credulity and would contradict its fundamental instruction that, "[i]n enacting a statute, it is presumed that … [a] just and reasonable result is intended." O.R.C. § 1.47(C).

In sum, the Court perceives nothing in § 4729.35 expressly stating or necessarily implying abrogation of common law public nuisance claims. Accordingly, the Pharmacy Defendants' motion to dismiss on that basis is denied.

B. Pharmacy Duties Under the CSA.

The Pharmacy Defendants next argue they are entitled to dismissal of Plaintiffs' claims because ***only*** their pharmacist-employees—and not also they, themselves—have a duty under the Controlled Substances Act to prevent diversion of opioids via illegitimate prescriptions. This contention is deeply troubling and, for the reasons below, the Court firmly rejects it.

In its *Opinion and Order Regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act* (Doc. #: 2483),[17] this Court held that, "as a matter of law, Section 1301.74 [of Title 21 of the Code of Federal Regulations] imposes a legal duty on registrants to design and operate a system to disclose to the registrant suspicious orders." Doc. #: 2483 at 15. Section 1301.74 applies specifically to non-practitioners—that is, manufacturers and distributors, but *not* pharmacies. The Pharmacy Defendants acknowledge that corporate *distributors* of opioids have a duty to prevent diversion by monitoring suspicious orders, but assert "there is no equivalent corporate-level obligation with respect to *dispensing*." Doc. #: 3340-1 at 14 (emphasis added).[18] Defendants contend, instead, that "the responsibility to guard against invalid prescriptions rests

[17] *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019).

[18] The Court previously described the distinction between distribution and dispensing as follows: "'distribution' involves movement of opioid products from (for example) a warehouse to a specific pharmacy, while 'dispensing' refers to the 'final step' in the distribution process, from the pharmacy to an individual patient." *Discovery Ruling No. 8* at 1 (Doc. #: 1055). Although many of the Pharmacy Defendants are also registered as distributors, this order pertains specifically to their role in dispensing.

with individual pharmacists, and ***only*** with individual pharmacists." *Id.* (emphasis in original). In other words, the Pharmacy Defendants now ask the Court to conclude that the CSA, as a matter of law, does not impose any obligation on a pharmacy-registrant, itself, to identify or investigate dubious prescriptions prior to filling them. The Court declines to do so, as this strained interpretation of the CSA would turn the fundamental purpose of the Act on its head.

In a prior opinion, the Court described the statutory and regulatory framework of the CSA and its implementing regulations. *See In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575, at *3 (Doc. #: 2483 at 5). In short, all persons who dispense controlled substances (including pharmacies) must register with the Attorney General.[19] 21 U.S.C. § 822. Generally, in the case of pharmacies, the Attorney General must issue them a registration so long as they are authorized to dispense controlled substances by and in the State where they practice. 21 U.S.C. § 823(f). However, the Attorney General may deny a registration if he deems it inconsistent with the public interest. *Id.*; *see also* 21 U.S.C. § 824(a)(4).

To help the Attorney General determine the public interest, the CSA provides a nonexclusive list of five factors the Attorney General must consider, including "[t]he applicant's experience in dispensing … controlled substances" and its "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances." 21 U.S.C. § 823(f)(2), (4). Chapter II of Title 21 of the Code of Federal Regulations further expands upon these general provisions. *See generally* 21 C.F.R. Ch. II.

The Regulations at Title 21, Chapter II have been properly promulgated pursuant to Congressional authorization and, thus, carry the full force and effect of law. *See In re Nat'l*

[19] The CSA expressly authorizes the Attorney General to regulate the distribution of controlled substances. In turn, the Attorney General delegated this authority to the DEA Administrator. *See John Doe, Inc. v. Gonzalez*, 2006 WL 1805685 at *1 (D.C. Cir. June 29, 2006); *United States v. Caudle*, 828 F.2d 1111, 1111 n.1 (5th Cir. 1987) (citing 38 FR 18380 (DEA Jul. 10, 1973)).

Prescription Opiate Litig., 2019 WL 3917575 at *3, *7 (Doc. #: 2483 at 6, 15) (citing *Chevron USA, Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843-844 (1984)). The CSA—as interpreted through these implementing regulations—is unequivocal:

> ***All*** applicants and registrants shall provide effective controls and procedures to guard against [i] theft ***and*** [ii] diversion of controlled substances.

21 C.F.R. § 1301.71(a) (emphasis added). The Court has previously explained that, "pursuant to this [Congressional] authorization, the DEA has promulgated regulations that set forth security requirements for registered manufacturers, distributors, and dispensers of controlled substances." *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575 at *3 (Doc. #: 2483 at 6) (citing 21 C.F.R. §§ 1301.71-77 (the "Security Requirements")).

The Pharmacy Defendants do not disagree that the CSA's Security Requirements apply to them. But they assert that, at least with respect to pharmacies, these regulations "only impose[] requirements for in-store physical security controls and ha[ve] never been understood to require a 'system' for monitoring prescriptions and disclosing 'suspicious orders of controlled substances.'" Doc. #: 3340-1 at 16 n.6. In other words, even though ***all*** other registrants (including their own pharmacist-employees) need to guard against theft ***and*** other species of diversion, the Pharmacy Defendants assert ***they*** need only guard against theft.

The Regulation's use of the word "and," however, unambiguously indicates that ***all*** registrants have an affirmative obligation to protect not only against diversion via theft but also other forms of diversion more broadly. To conclude otherwise, as the Pharmacy Defendants suggest, disregards the plain meaning of the text, undermines the purpose of the CSA, and would allow a frightening abdication of responsibility. Furthermore, as explained below, the CSA ***explicitly*** requires pharmacies to collect prescription data and use it to monitor for questionable prescriptions that might lead to diversion.

1. Statutory Obligations of Registrants.

The Pharmacy Defendants are certainly correct that the CSA includes provisions addressing physical theft of drugs from pharmacies. Specifically, the Regulation's Security Requirements lay out a non-exhaustive list of controls that a registrant must implement in order to store and dispense Schedule II controlled substances safely at their stores. *See* 21 C.F.R. § 1301.75-76.

But it is equally certain that the Pharmacy Defendants' statutory obligations do not end there. With respect to diversion more broadly, the CSA and its implementing regulations impose many other obligations on registrants—***all*** registrants—that serve to advance the CSA's overall stated purpose of preventing diversion. For example, the CSA imposes specific record-keeping requirements on registrants who handle controlled substances. Specifically, a pharmacy-registrant must, at a minimum and among other things, record and maintain:

> the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the [controlled] substance on behalf of the dispenser.

21 C.F.R. § 1304.22(c). Whatever other information a pharmacy may choose to collect about its own dispensing practices, those of its stores, or those of its pharmacists, the CSA mandates the collection and retention of specific data-points that would inarguably be useful to the pharmacy (or the DEA) in identifying suspicious prescribing and dispensing activity. This record-keeping requirement is clearly intended as a guard against diversion. *See Medicine Shoppe-Jonesborough*, 73 FR 364-01, 365 (DEA Jan. 2, 2008) (because "Respondent [retail ***pharmacy***] violated federal law and DEA regulations by failing to maintain complete and accurate records," "revocation of its registration is necessary to protect the public interest"), *petition for review denied, Med. Shoppe-Jonesborough v. Drug Enf't Admin.*, 300 F. App'x 409, 411 (6th Cir. 2008) ("Medicine Shoppe

fell short of meeting its duty to maintain accurate records of the controlled substances it dispensed."). It would undermine the entire purpose of the CSA (and defy logic) for the Act to require a pharmacy to collect the dispensing data listed in § 1304.22(c), but then allow the pharmacy to ignore this data when fulfilling its fundamental obligation to guard against diversion.

In addition to the Security Requirements and record-keeping requirements, the CSA also mandates that a pharmacy-registrant must employ a properly licensed and trained pharmacist. The Pharmacy Defendants, as non-pharmacist corporate entities, attempt to interpose this requirement to insulate themselves from liability. But the result the Pharmacy Defendants espouse can only be reached through a strained reading of the CSA as a whole.

Under the CSA, a pharmacy is itself a "Practitioner." *See* 21 U.S.C. § 802(21) ("The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator, ***pharmacy***, hospital, or other person licensed, registered, or otherwise permitted … to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice.") (emphasis added). Further, a pharmacy is also a "dispenser." *See* 21 C.F.R. § 1300.01 ("Dispenser means an individual practitioner, institutional practitioner, ***pharmacy*** or pharmacist who dispenses a controlled substance.") (emphasis added); *see also* 21 U.S.C. § 802(10) (a dispenser is "a practitioner who so delivers a controlled substance to an ultimate user").

The Pharmacy Defendants attempt to draw a distinction between the roles of a pharmacist and a pharmacy. The Pharmacy Defendants then insist that individual, licensed pharmacists, and only those pharmacists, bear responsibility for dispensing controlled substances improperly. *See* Doc. #: 3340-1 at 17 (citing 21 C.F.R. § 1306.04(a)). But the CSA does not make this distinction. ***Both*** pharmacists and pharmacies are "practitioners" under the Act. And ***both*** are "dispensers."

Accordingly, both pharmacists and pharmacies bear all the obligations imposed upon practitioners and dispensers. And, the statutory definitions of these two terms—especially the statutory definition of "practitioner"—expressly anticipate that a pharmacy has the ability to dispense controlled substances in the course of its own professional practice. Thus, under the CSA, any ***person*** (which, to be clear, includes corporate entities) who dispenses or delivers a controlled substance to an ultimate user must adhere to all of the obligations imposed by the Act.

This understanding is further confirmed by the language of Section 1306.04(a):

> The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with ***the pharmacist*** who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and ***the person*** knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a) (emphasis added). Put plainly, although this regulation recognizes it is "***the pharmacist***" who physically hands the controlled substance over to the patient, the regulation intentionally and explicitly subjects ***the person***—which is a much broader term, applying not just to the pharmacist but also to the pharmacy—to penalties for violation of the CSA. This interpretation has been adopted and ratified by the DEA and at least one other district court. *See Top RX Pharmacy*; *Decision and Order*, 78 FR 26069-01, 26082 (DEA May 3, 2013) ("The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself.") (citing multiple agency rulings);[20] *see also United States v. Appalachian Reg'l*

[20] The Pharmacy Defendants insist that, "[a]lthough DEA has sometimes referred to the ***pharmacist's*** responsibility as the ***pharmacy's*** responsibility, that occasional imprecision does not create an independent regulatory responsibility for a pharmacy." Doc. #: 3340-1 at 18 (citations omitted) (emphasis added). However, given the large number of agency actions that refer to a pharmacy-registrant's corresponding responsibility, the Court finds it highly unlikely that the Agency is so routinely "imprecise." This Court assumes, rather, that the Agency knows how to draw a distinction between a pharmacist and a pharmacy and, to the extent an ALJ or the Administrator wrote that a pharmacy has a responsibility to ensure prescriptions are legitimate, they did so intentionally. *See, e.g., Top RX Pharmacy;*

Healthcare, Inc., 246 F. Supp. 3d 1184, 1189-90 (E.D. Ky. 2017) (finding "nothing inconsistent about articulating the responsibilities of individual practitioners and pharmacists while simultaneously indicating that other entities may be subject to penalties for their role in issuing and filling invalid prescriptions.").

Seeking support outside of the CSA itself, the Pharmacy Defendants also turn to Ohio law, asserting it supports their contention that "[o]nly a licensed pharmacist—not the non-pharmacist corporate owner of a pharmacy—may engage in the practice of pharmacy." Motion at 15. Specifically, the Pharmacy Defendants rely on O.R.C. § 4729.27, which states: "A person not a pharmacist, who owns, manages, or conducts a pharmacy, shall employ a pharmacist to be in full and actual charge of such pharmacy." The Pharmacy Defendants submit this language indicates that only a pharmacist can be held liable for the dispensing practices of a pharmacy, because "[q]uestioning the validity of a prescription requires … specialized knowledge, judgment, and skill, and is a task that Pharmacy Defendants cannot lawfully usurp from their pharmacists." *Id.*

This logic fails. Ohio controlled substance law largely mirrors the federal scheme and sets out identical obligations. In Ohio, the Pharmacy Defendants are classified as "Terminal Distributors." The Ohio Revised Code defines "Terminal Distributor of Dangerous Drugs" as:

Decision and Order, 78 FR 26069-01, 26082 (DEA May 3, 2013) ("a pharmacist ***or pharmacy*** may not dispense a prescription in the face of a red flag") (emphasis added); *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195, Decision and Order*, 77 FR 62316-01, 62343 (DEA Oct. 12, 2012) ("on various occasions, each of the Respondents [***pharmacies***] dispensed controlled substances in the face of red flags that were or should have been recognized"); *Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies*, 75 FR 61613, 61617 (DEA Oct. 6, 2010) ("Providing a copy [of the agency agreement] to ***pharmacies*** … may assist those ***pharmacies*** with their corresponding responsibility regarding the dispensing of controlled substances."); *Medicine Shoppe-Jonesborough*, 73 FR 364-01, 383 ("Here again, the evidence establishes that Mr. Street [a pharmacist] ***and Respondent [a pharmacy]*** failed to comply with their corresponding responsibility under federal law."); *United Prescription Services, Inc. Revocation of Registration*, 72 FR 50397-10, 50409 (DEA Aug. 31, 2007) ("***Respondent [pharmacy]*** thus violated 21 CFR 1306.04 by filling these [illegal] prescriptions."); *Issuance of Multiple Prescriptions for Schedule II Controlled Substances*, 72 FR 64921, 69424 (DEA Nov. 19, 2007) ("physicians ***and pharmacies*** have a duty as DEA registrants to ensure that their prescribing and dispensing of controlled substances occur in a manner consistent with effective controls against diversion and misuse.") (citing *Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Controlled Substances*, 70 FR 50408 (DEA Aug. 26, 2005)).

> a ***person*** who is engaged in the sale of dangerous drugs at retail, or any person, ***other than a … pharmacist***, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption.
>
> "Terminal distributor" includes ***pharmacies*** … who procure dangerous drugs for sale or other distribution ***by or under the supervision of a pharmacist*** … authorized by the state board of pharmacy.

O.R.C. § 4729.01(Q) (emphasis added). Furthermore, the licensure requirements for Terminal Distributors of Dangerous Drugs, pursuant to O.R.C. § 4729.55, require that:

> No license shall be issued to an applicant for licensure as a terminal distributor of dangerous drugs unless the applicant has furnished satisfactory proof to the state board of pharmacy that:
>
> * * *
>
> (B) A pharmacist … authorized by the board … will maintain supervision and control over the possession and custody of dangerous drugs and controlled substances that may be acquired by or ***on behalf of the applicant***.
>
> * * *
>
> (D) Adequate safeguards are assured that the applicant will ***carry on the business of a terminal distributor*** of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner.

O.R.C. § 4729.55 (emphasis added).

Combined, these provisions mean that a pharmacy owner, who is not him- or herself a licensed pharmacist, must employ a licensed pharmacist as a control against diversion, and the pharmacy must conduct its business in a way that allows its pharmacist to properly dispense the pharmacy-licensee's controlled substances on its behalf. These provisions cannot be read to mean that pharmacy owners who ***are not themselves pharmacists*** are absolved of responsibility for their own dispensing practices simply because they must employ a pharmacist, whereas pharmacy

owners who ***are pharmacists***—and thus need not employ a separate pharmacist—are not.[21] Such a reading would undermine the purpose of Ohio's controlled substance law, and would disincentivize licensed pharmacists from owning and operating their own pharmacies.

Finally, the Ohio Revised Code specifically contemplates disciplinary action against ***pharmacies*** that "[c]eas[e] to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55." O.R.C. § 4729.57(B)(7). That is, if a ***pharmacy*** fails to conduct its business in a way that allows its pharmacists to be effective, it is in violation of Ohio controlled substance laws.[22] The Pharmacy Defendants' invocation of Ohio law in support of their attempt to avoid their legal obligations under the CSA is unavailing.

In sum, the Court concludes the Pharmacy Defendants have not shown that sole responsibility for their dispensing practices rests with their pharmacist-employees. Rather, the CSA makes clear that any ***person***, which includes a pharmacy itself, who knowingly fills or allows to be filled an illegitimate prescription is in violation of the Act.

2. System Requirement.

Beyond the aforementioned statutory obligations, Plaintiffs assert the CSA also imposes duties on the Pharmacy Defendants to maintain systems, policies, or procedures to identify prescriptions that bear indicia ("red flags") that the prescription is invalid, or that the prescribed

[21] Such a reading would be tantamount to a statutory "safe harbor" by providing that a pharmacy owner could not be held liable for its role in dispensing controlled substances simply by employing a pharmacist. Employment of a properly licensed pharmacist must be read as a feature of the law, not a way to subvert it.

[22] The Court notes that, under Ohio law: (1) a Terminal Distributor is ***not a pharmacist***, *see* O.R.C. § 4729.01(Q); (2) a Terminal Distributor is engaged in the Retail Sale of dangerous drugs, *see id.*; (3) a Retail Seller is "***any person*** that sells any dangerous drug to consumers without assuming control over and responsibility for its administration, *see* § 4729.01(M); and (4) "sell" includes "***any transaction made by any person***" that effectively transfers the dangerous drug to another. *See* § 4729.01(J). Thus, the Ohio Revised Code expressly contemplates that a pharmacy's business includes dispensing of dangerous drugs to consumers.

drugs may be diverted for illegitimate use. The Pharmacy Defendants admit an equivalent duty exists for manufacturers and distributors with respect to suspicious ***orders***, but insist no such duty exists for pharmacies with respect to suspicious ***prescriptions***.[23] Defendants are wrong.

There is no question that dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances.[24] The DEA, in Agency decisions interpreting its regulations, routinely conducts a "red flag analysis." In fact, the Agency has even articulated the specific elements of a *prima facie* violation of a pharmacy-registrant's responsibility under 21 C.F.R. § 1306.04(a) using the term "red flag." *See Holiday CVS*, 77 FR at 62341 ("to show a violation of a corresponding responsibility, the Government must establish that: (1) the Respondent [a pharmacy] dispensed a controlled substance; (2) a ***red flag*** was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the ***red flag*** was not resolved conclusively prior to the dispensing of the controlled substance.") (emphasis added).[25] Agency

[23] The Court notes that many, if not all, of the Pharmacy Defendants maintain (or did maintain during the relevant time period) DEA registrations as distributors as well.

[24] The Pharmacy Defendants assert that any analogy between (i) a duty of dispensers to identify and resolve red flags before filling subscriptions and (ii) a duty of distributors to identify and conduct due diligence prior to shipping suspicious orders, is "unfounded and unworkable." Doc. #: 3379at 5 (referring to the Court's August 19, 2019 *Opinion and Order Regarding the CSA* (Doc. #: 2483)). But Agency decisions have made abundantly clear there exists a duty of dispensers to identify and resolve red flags before filling opioid prescriptions. Therefore, the Court need not rely upon "analogy" to conclude this duty exists.

[25] Regarding the second prong recited in *Holiday CVS*—whether "a red flag was or should have been recognized at or before the time the controlled substance was dispensed"—the DEA "has consistently interpreted [section 1306.04(a)] as prohibiting a pharmacist from filling a prescription for a controlled substance when he either ***knows or has reason to know*** that the prescription was not written for a legitimate medical purpose." *E. Main St. Pharmacy*, 75 FR 66149-01, 66163 (DEA Oct. 27, 2010) (citing agency and Sixth Circuit precedent) (internal quotations omitted). The Pharmacy Defendants assert that, absent identification by Plaintiffs of any *specific* prescription filled by Defendants that they knew or should have known was illegitimate, Plaintiffs do not state viable claims. Plaintiffs have alleged, however, that the Pharmacy Defendants had reason to know that at least some of the prescriptions they dispensed were illegitimate. At the motion to dismiss stage, with factual allegations in the complaint accepted as true and viewed in favor of the nonmoving party, the Court easily concludes that Plaintiffs allegations are plausible.

precedent, in analyzing whether a registrant properly identified and resolved red flags, uses a combination of factors (2) and (4) of 21 U.S.C. 823(f) as the statutory basis for the requirement.[26]

Many of the red flags that the Agency examines (which a registrant should have at least identified and, if possible, resolved) include indicia that would be very difficult, if not impossible, for a human pharmacist to identify consistently absent a system to aggregate, analyze, and provide feedback to the pharmacist about the prescription.[27] In other words, some prescriptions are not suspicious on their face but raise bright red flags when compared with other prescriptions in a database. One example of such a red flag is "'pattern prescribing,' defined as 'prescriptions for the same drugs, the same quantities[,] coming in from the same doctor." *Holiday CVS*, 77 FR at 62344. Identifying prescriptions presented over time for the same drugs or combinations of drugs, in the same quantities, issued by the same doctor (and possibly presented to different pharmacists in different stores owned by the same pharmacy), would test the limits of human memory; this red flag would be nearly impossible for any individual pharmacist to discern absent some global mechanism for reference to other prescriptions. However, given that a ***pharmacy-registrant*** is required to collect the specific data needed to identify exactly such a pattern, the pharmacy—not the pharmacist—is in the best position to identify such a red flag (or at least provide the pharmacist with data reports to do so). Indeed, the fact that the DEA has revoked registrations of ***pharmacies***

[26] Those factors are "[2] The applicant's experience in dispensing … controlled substances," and "[4] Compliance with applicable State, Federal, or local laws relating to controlled substances." 21 U.S.C. § 823(f)(2), (4). *Compare Holiday CVS*, 77 FR at 62341-42 (relying on factor (4)); *with E. Main St. Pharmacy*, 75 FR 66149-01, 66150 (DEA Oct. 27, 2010) (relying on factor (2)). Frequently, the two factors are analyzed together. *See, e.g.*, *Top RX Pharm*., 78 FR at 26081.

[27] The DEA has unequivocally accepted certain "red flag" indications that some prescriptions are suspicious, and many of these red flags have nothing to do with the specialized knowledge or training of a pharmacist; rather, these red flags are patterns in prescription data that a human pharmacist normally would never see. Computer algorithms, when applied to sufficient data (which the pharmacies are required to collect), are particularly well-suited to identify these patterns.

for failure to identify such red flags necessarily means pharmacies are required to look for them, which can only be done by putting into place systems to identify them.

The Pharmacy Defendants assert they cannot be responsible for identifying red flags because they do not have the requisite "specialized knowledge, judgment, and skill" to engage in the practice of pharmacy. Doc. #: 3340-1 at 15 (citing O.R.C. § 4729.01(B)). But the Pharmacy Defendants do have an obligation under the CSA to employ someone who does have and can exercise appropriate professional knowledge, judgment, and skill on their behalf. The same is expressly true under Ohio law. *See* O.R.C. § 4729.55(D). Pharmacies also have an obligation under Ohio law to "allow[] pharmacists … to practice pharmacy in a safe and effective manner." *Id.* These objectives are accomplished fully only when a pharmacy actually uses the data it is required to collect under 21 C.F.R. § 1304.22(c) to provide a tool otherwise unavailable to its pharmacists.

The Pharmacy Defendants also assert the CSA cannot impose an obligation on them to identify red flags because, as corporate-entity non-pharmacists, they cannot override the professional decisions of their pharmacists to determine the propriety of a prescription. *See* Doc. #: 3340-1 at 16. But nothing about using data to identify a suspicious prescription would work to override a pharmacist's ability to determine if the prescription was proper. To the contrary, a data-driven analysis should assist and work in synergy with a pharmacist's expertise. Ultimately, pharmacists cannot best employ their "professional knowledge, judgment, and skill" to prevent diversion if their pharmacy-employer does not provide useful access to the "red-flag-revealing" data it has gathered.

Although the CSA is not perfectly clear about what a pharmacy-registrant must do with the prescription data it must collect, what is clear is that a pharmacy is required to: (1) collect and

maintain specific records and data regarding its dispensing activity; (2) employ a properly licensed pharmacist; and (3) properly dispense controlled substances and avoid diversion. Therefore, both the pharmacy and the pharmacist must cooperatively identify and resolve "red flags" prior to dispensing controlled substances. The Court concludes these requirements collectively mean that the Pharmacy Defendants cannot collect data as required by the statute, employ a licensed pharmacist as required by the statute, identify red flags as required by Agency decisions, but then do nothing with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled. Possessing, yet doing nothing with, information about possible diversion would actually ***facilitate*** diversion, and thus violate the CSA's fundamental mandate that "***All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances***." 21 C.F.R. § 1301.71(a) (emphasis added).

In sum, the Court concludes the Pharmacy Defendants have failed to meet their burden of demonstrating there is no corporate-level obligation to design and implement systems, policies, or procedures to identify red flag prescriptions. And the Pharmacy Defendants' ultimate argument—that they cannot be liable to Plaintiffs because only their pharmacist-employees are responsible for preventing diversion of opioids via illegitimate prescriptions—is premised upon a tortured reading of the CSA and its regulations. Because Defendants' reading of the CSA is antithetical to its very purpose, the Court rejects Defendants' positions.

C. Ohio Absolute Public Nuisance.

Plaintiffs allege common law claims for absolute public nuisance based on the Pharmacy Defendants' alleged intentional and unlawful misconduct involving both *distribution* and *dispensing* of prescription opioids. To the extent these claims are based on *dispensing* activities,

the Pharmacy Defendants argue the claims are simply not cognizable under Ohio law of public nuisance.[28] Doc. #: 3340-1 at 23-26. For the reasons stated below, the Court rejects this argument.

A "public nuisance" is an unreasonable interference with a right common to the general public, including the rights to public health and public safety.[29] *Cincinnati v. Deutsche Bank Nat'l Trust Co.*, 863 F.3d 474, 477 (6th Cir. 2017); C*incinnati v. Beretta USA Corp.*, 768 N.E.2d 1136, 1142 (Ohio 2002). Ohio law recognizes two categories of nuisance claims—"absolute" and "qualified"—and the distinction between the two depends on the conduct of the defendant. *Nottke v. Norfolk S. Ry. Co.*, 264 F. Supp.3d 859, 862 (N.D. Ohio 2017) (citation omitted). An "absolute" nuisance, also called a nuisance *per se*, is based on culpable and intentional or unlawful conduct by the defendant resulting in harm.[30] *Taylor*, 55 N.E. 2d at 727-732; *Barnett v. Carr*, 2001 WL 1078980, at *11 (Ohio Ct. App. Sept. 17, 2001). A "qualified" nuisance, on the other hand,

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[28] As to claims based on the Pharmacies' *distribution* activities, this Court has previously found similar allegations sufficiently support an absolute public nuisance claim under Ohio law. *See, e.g., In re Nat'l Prescription Opiate Litig.*, 440 F. Supp. 3d at 805-08 (Doc. #: 3177 at 41-47) (plaintiffs sufficiently pled Ohio absolute public nuisance claims based, in part, on defendants' alleged failure to maintain effective controls with respect to distribution activities); *Opinion and Order Regarding Manufacturers' Summary Judgment Motion in Track One, In re Nat'l Prescription Opiate Litig.*, 406 F. Supp. 3d 672, 672-76 (N.D. Ohio 2019) (Doc. #: 2578 at 1-7) (material fact issues regarding defendants' alleged failure to maintain anti-diversion controls precluded summary judgment on Ohio absolute public nuisance claims); *see also Opinion and Order Regarding Motions to Dismiss West Boca, In re Nat'l Prescription Opiate Litig.*, 2020 WL 1669655, at *17-18 (N.D. Ohio Apr. 3, 2020) (Doc. #: 3253 at 29-33) (same under Florida law); *Report and Recommendation Regarding Motions to Dismiss Blackfeet Tribe*, *In re Nat'l Prescription Opiate Litig.*, 2019 WL 2477416, at *9-18 (N.D. Ohio Apr. 1, 2019) (Doc. #: 1500 at 26-34) (same under Montana law), *adopted by* 2019 WL 3737023, at *9-11 (N.D. Ohio June 13, 2019) (Doc. #: 1680 at 16-20); *Report and Recommendation Regarding Motions to Dismiss Muscogee Nation*, *In re Nat'l Prescription Opiate Litig.*, 2019 WL 2468267, at *26-33 (N.D. Ohio Apr. 1, 2019) (Doc. #:1499 at 50-62) (same under Oklahoma law), *adopted by* 2019 WL 3737023, at *9-11 (N.D. Ohio June 13, 2019) (Doc. #: 1680 at 16-20).

[29] The Court has previously ruled claims similar to the Counties' sufficiently pled interference with a common public right to be free from the negative consequences allegedly suffered as a result of the opioid epidemic. *See* Doc. #: 1500 at 28-30 (Montana law), *adopted by* Doc. #: 1680 at 16-20; Doc. #: 1499 at 50-62 (Oklahoma law), *adopted by* Doc. #: 1680 at 16-20; *see also* Doc. #: 2578 at 3-4 ("A factfinder could reasonably conclude that [plaintiffs'] evidence demonstrates an interference with public health and public safety rights.") (Ohio law).

[30] An "absolute" nuisance can also be based on nonculpable conduct by the defendant that results in "accidental harm for which, because of the hazards involved, the law imposes strict or absolute liability notwithstanding the absence of fault." *Taylor*, 55 N.E.2d at 727; *Nottke*, 264 F.Supp.3d at 862; *Angerman v. Burick*, No. 02CA0028, 2003 WL 1524505, at *2 (Ohio Ct. App. March 26, 2003). Plaintiffs here do not allege an absolute public nuisance based on inherently dangerous conduct.

involves harm caused by the defendant's negligence. *Taylor*, 55 N.E.2d at 727-732; *Angerman*, 2003 WL 1524505, at *2.

Here, the Plaintiffs assert absolute public nuisance claims based on alleged *intentional* and *unlawful* dispensing conduct. *See* Doc. #: 3327 at ¶620. The Pharmacy Defendants, however, contend the Plaintiffs' allegations "fundamentally sound in negligence" and do not sufficiently describe intentional or unlawful conduct necessary to support an absolute nuisance action. Doc. #: 3340-1 at 23-25. More specifically, the Defendants contend Plaintiffs merely allege that the Pharmacies engaged in lawful conduct and "should have innovated new ways to identify and prevent diversion." *Id.* at 24-25.

Contrary to the Pharmacy Defendants' contention, Plaintiffs clearly allege Defendants engaged in *intentional* conduct to dispense opioids in a manner that caused an oversupply of highly addictive drugs in Plaintiffs' communities. Plaintiffs allege the Pharmacy Defendants: (i) were "keenly aware of the oversupply of prescription opioids;" (ii) willfully and "systematically ignored red flags that they were fueling a black market;" (iii) required and rewarded speed and volume by opioid-dispensing employees, while minimizing standards of safety and care; (vi) purposefully implemented performance metrics and prescription quotas to increase dispensing of opioids; (v) "facilitated the supply of far more opioids than could have been justified to serve a legitimate market;" (vi) knowingly worked in concert with opioid manufacturers "to ensure that false messaging surrounding the treatment of pain and the true addictive nature of opioids was consistent and geared to increase profits for all stakeholders;" (vii) "worked together to ensure that the opioid quotas allowed by the DEA remained artificially high;" and (viii) falsely assured the public that Defendants were working to curb the opioid epidemic. Doc. #: 3327 at ¶¶74-77, 81, 413-425, 454-478, 480-494, 600-606, 609-611.

The Pharmacy Defendants contend these allegations are insufficient to show they intended to cause the harms allegedly suffered by the Plaintiffs. Doc. #: 3340-1 at 25. To meet the requisite intent for an absolute nuisance, however, a plaintiff need not allege the defendant intended to create the precise alleged nuisance; rather, plaintiff only need allege the defendant "intended to bring about the conditions which are in fact found to be a nuisance." *Nottke*, 264 F. Supp.3d at 863 (quoting *Angerman*, 2003 WL 1524505 at *2). Stated otherwise, "[w]here the harm and resulting damage are the necessary consequences of just what the defendant is doing, or is incident to the activity itself or the manner in which it is conducted, the law of negligence has no application and the rule of absolute liability applies." *Taylor*, 55 N.E.2d at 727; *see also In re Nat'l Prescription Opiate Litig.*, 406 F. Supp. 3d at 675-76 (Doc. #: 2578 at 5-7) (material fact issues regarding the opioid manufacturers' intent precluded summary judgment for defendants on absolute nuisance claims in the Track One cases).

Here, Plaintiffs allege the conditions created by the Pharmacies' intentional conduct – that is, oversupply of opioids in Plaintiffs' communities – necessarily resulted in the devastating consequences that Plaintiffs allegedly suffered because of the opioid epidemic. Doc. #: 3327 at ¶¶573-599, 621-626, 633-637. Accepting these allegations as true and construing them in the light most favorable to Plaintiffs, the Court finds Plaintiffs have fairly and sufficiently stated plausible claims for absolute public nuisance based on the Pharmacy Defendants' alleged intentional conduct involving their dispensing activities. *See Nottke*, 264 F. Supp.3d at 863-864 (plaintiffs stated a facially plausible claim for absolute nuisance where the harms allegedly suffered were the necessary consequence of defendant's intentional operation of braking systems that repeatedly produced "very loud, unbearable high-pitched squealing" sounds); *Angerman*, 2003 WL 1524505, at *1-3 (where defendants intentionally built and operated a motocross track that generated a great

deal of noise as an unavoidable byproduct of their intentional activity, the law of absolute public nuisance applied).

Additionally, as discussed in the previous section, Plaintiffs have sufficiently alleged the Pharmacy Defendants engaged in unlawful dispensing conduct by failing to comply with statutory and regulatory requirements to provide effective controls against diversion, including ensuring proper dispensing of controlled substances. These allegations provide an additional and alternative basis to support the absolute nuisance claims. *See In re Nat'l Prescription Opiate Litig.*, 406 F. Supp. 3d at 676 (Doc. #: 2578 at 7) (evidence of the opioid manufacturers' failure to comply with their anti-diversion obligations under the CSA precluded summary judgment in Track One on plaintiffs' absolute public nuisance claims based on unlawful conduct); *Kramer v. Angel's Path, LLC*, 882 N.E.2d 46, 53 (Ohio Ct. App. 2007) (strict liability is imposed under absolute nuisance "when there is 'the violation of law resulting in a civil wrong or harm,' especially when a safety statute is violated") (quoting *Taylor*, 55 N.E.2d at 728).[31]

The Pharmacy Defendants also argue that, as a matter of law, an absolute nuisance theory cannot apply because their dispensing conduct was licensed, authorized, and regulated under the CSA. Doc. #: 3340-1 at 24 n.24, 25; Doc. #: 3379 at 14. This Court has previously rejected identical arguments, finding that, under Ohio law, "'safe harbor' immunity from absolute nuisance liability is available only to those who perform in accordance with their applicable licensing

[31] In their reply brief, the Pharmacy Defendants argue that, even if their alleged dispensing conduct was *unlawful*, an absolute nuisance theory would not apply, because the CSA and its implementing regulations merely set forth a general duty to exercise ordinary care under the circumstances and do not set forth rules requiring or prohibiting the performance of specific acts. *See* Doc. #: 3379 at 13 (citing *Taylor*, 55 N.E.2d at 733; and *Natale v. Everflow E., Inc.*, 959 N.E.2d 602, 609-10 (Ohio Ct. App. 2011)). The Court declines to address arguments raised for the first time in a reply brief. *Ross v. Choice Hotels Int'l, Inc.*, 882 F.Supp.2d 951, 958 (S.D. Ohio 2012). Moreover, the Court disagrees with the Pharmacy Defendants' contention that the CSA and its regulations merely establish a general duty to exercise reasonable care. As discussed in the previous section, the CSA statutory and regulatory framework imposes specific obligations on pharmacies to protect against the diversion of controlled substances.

regulatory obligations." *In re Nat'l Prescription Opiate Litig.*, 440 F. Supp. 3d at 808 (Doc. #: 3177 at 45-47). The same analysis applies here. As discussed, Plaintiffs allege the Pharmacy Defendants did not comply with the regulatory scheme but, rather, violated it. Accordingly, the Court declines to dismiss the absolute nuisance claims on this ground. *Id.*[32]

Last, the Pharmacy Defendants assert Plaintiffs cannot pursue liability based on Defendants' First-Amendment-protected participation in trade groups that lobbied against additional regulation of the opioid supply chain. Completely aside from any alleged lobbying or trade group activities, however, Plaintiffs allege ample intentional and unlawful conduct by Defendants to support their absolute nuisance claims. Moreover, this Court has previously found that evidence of lobbying activities may be admissible for other purposes, such as to show motive or intent. *See Evidentiary Order,* Doc. #: 3058 at 51-53. On this record, the Court concludes Plaintiffs have sufficiently stated common law claims for absolute public nuisance based on the Pharmacy Defendants' alleged dispensing activities.

D. Proximate Causation – Learned Intermediary Doctrine.

Finally, the Pharmacy Defendants argue that, under the learned intermediary doctrine, the intervening conduct of prescribing medical professionals breaks the causal chain between the Pharmacy Defendants' conduct and the Plaintiffs' injuries. Doc. #: 3340-1 at 26.

The Court previously found allegations similar to Plaintiffs' here sufficient to overcome a motion to dismiss on proximate cause grounds.[33] Specifically, the Court declined to find, under

[32] *See also In re Nat'l Prescription Opiate Litig.*, 2020 WL 1669655, at *18 (Doc. #: 3253 at 32-33) (allegations of conduct incompatible with defendants' statutory authority stated an actionable public nuisance claim) (Florida law); *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3737023, at *10 (Doc. #: 1680 at 17-18) ("to allege an absolute public nuisance, the Tribe needed only to allege that Distributors exceeded their statutory authority") (Montana law).

[33] *See Opinion and Order in Broward*, *In re Nat'l Prescription Opiate Litig.*, 2020 WL 1986589, at *5 (N.D. Ohio Apr. 27, 2020) (Doc. #: 3274 at 8–9); *Opinion and Order in West Boca*, *In re Nat'l Prescription Opiate Litig.*, 2020

Florida and Oklahoma law, a doctor's prescribing decision breaks the causal chain between the Pharmacies' dispensing conduct and the plaintiffs' injuries as a matter of law. *See In re Nat'l Prescription Opiate Litig.*, 2020 WL 1669655, at *7 (Doc. #: 3253 at 12) (finding Florida law does not "relieve a pharmacist … from all responsibility stemming from the filling of prescriptions written by doctors"); *In re Nat'l Prescription Opiate Litig.*, 2020 WL 1986589, at *5 (Doc. #: 3274 at 8–9) (same); *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3737023, at *5 (Doc. #: 1680 at 9) ("[T]he Court is not convinced that the learned intermediary doctrine [under Oklahoma law] applies to the causal chain that has been alleged by the Muscogee Nation.").[34] In each instance, the Court noted that causation should be left to the trier of fact.[35]

Ohio law calls for the same result. Ohio courts apply the learned intermediary doctrine in strict products liability cases to shift a prescription drug manufacturer's duty to warn onto the prescribing physician, if the manufacturer has adequately warned the physician. *Tracy v. Merrell Dow Pharms., Inc.*, 569 N.E.2d 875, 878 (Ohio 1991). This shift recognizes manufacturers and physicians have distinct relationships with product users and are in different positions to issue warnings regarding a product. *See id.* at 878 ("The rationale behind [the doctrine] is that the physician stands between the manufacturer and the patient…."); *see also Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 840 (Ohio 1981) ("A direct relationship between the manufacturer and the patient does not arise as a result of the provision of [warning] brochures.").

WL 1669655, at *7 (Doc. #: 3253 at 10-11); *Opinion and Order in Tribal Track*, *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3737023, at *4-6 (Doc. #: 1680 at 7-10); *Opinion and Order in Cleveland Bakers*, *In re Nat'l Prescription Opiate Litig.*, 440 F. Supp. 3d at 797, 812-813 (Doc. #: 3177 at 27-54).

[34] The Court has also concluded the Pharmacies cannot transfer to prescribers their liability (if any) to Plaintiffs, because Plaintiffs' liability theory relies on legal obligations and evidence independent of prescriber conduct. *Order Regarding Plaintiffs' Motion to Strike or Sever Third-Party Complaints*, *In re Nat'l Prescription Opiate Litig.*, 2020 WL 1526726, at *2-3 (N.D. Ohio Mar. 31, 2020) (Doc. #: 3246 at 4–5).

[35] *See In re Nat'l Prescription Opiate Litig.*, 2020 WL 1669655, at *5 (Doc. #: 3253 at 8); *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3737023, at *5 (Doc. #: 1680 at 8).

These cases, on which the Pharmacy Defendants rely, confirm the learned intermediary doctrine is wholly inapplicable here. Plaintiffs are not seeking to hold the Defendants liable for personal injuries to opioid users for harms caused by products or related warnings. Plaintiffs' public nuisance claims instead pertain to broad harms to the public allegedly caused by the Pharmacies' dispensing conduct that implicates legal obligations independent of manufacturers, physicians, or any other participant in the opioid supply chain. The Pharmacy Defendants have not identified any legal authority that shifts their obligation to prevent diversion to any other person or entity, or otherwise establishes that prescribers are an intervening or superseding cause of Plaintiffs' alleged injuries.[36]

Finally, Ohio law instructs that proximate cause is ordinarily a question of fact for the jury. *Brondes Ford*, *Inc. v. Habitec Sec.*, 38 N.E.3d 1056, 1086 (Ohio Ct. App. 2015). Because Defendants have not demonstrated Plaintiffs' allegations of proximate cause fail as a matter of law, the Court declines to dismiss Plaintiffs' claims.

IV. Previously Adjudicated Issues.

In the final section of their Motion, the Pharmacy Defendants expressly incorporate by reference their and other defendants' briefing on various substantive motions previously ruled on by this Court in Track One. In response, the Track Three Plaintiffs incorporate by reference the responsive briefing on those motions as well. Although the Pharmacy Defendants assert the Court

[36] Indeed, the Court questions whether, as Defendants assert, prescribers' conduct is in fact situated *between* the Pharmacies' relevant conduct and Plaintiffs' alleged injuries, such that the prescribers' conduct could be an intervening or superseding cause of the injuries. Even if some of the Pharmacies' alleged culpable conduct occurs before a doctor writes an opioid prescription (for example, creating opioid dispensing policies), Plaintiffs' allegations also include conduct that necessarily occurs after doctors write prescriptions. *See* Doc. #: 3327 at ¶¶83–85 ("Pharmacies failed … to conduct adequate internal or external reviews of their opioid sales to identify patterns regarding prescriptions that should not have been filled, or … failed to take any meaningful action as a result").

erred in these rulings, they do not seek reconsideration and only assert they would like to have these prior arguments preserved for appellate review. Accordingly, the Court will not reconsider its prior rulings at this time, but the relevant briefs shall be part of the judicial record in these Track Three cases.[37]

V. Conclusion.

The Pharmacy Defendants have not shown Plaintiffs failed to state a claim for which relief can be granted. Accordingly, *Pharmacy Defendants' Motion to Dismiss*, Doc. #: 3340, is **DENIED**.

IT IS SO ORDERED.

/s/ Dan Aaron Polster Augst 6, 2020
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

[37] The specific documents the parties ask to incorporate are:

- Doc. #: 497 – Pharmacy Defendants' Motion to Dismiss;
- Doc. #: 491 – Distributor Defendants' Motion to Dismiss;
- Doc. #: 654 – Plaintiffs' Opp. to Defs.' Motion to Dismiss;
- Doc. #: 1874 – Pharmacy Defendants' Motion for Summary Judgment on Statute of Limitations;
- Doc. #: 1883 – Pharmacy and Distributor Defendants' Motion for Summary Judgment on Preemption;
- Doc. #: 1885 – Pharmacy Defendants' Motion for Summary Judgment on Causation;
- Doc. #: 2171 – Plaintiffs' Opp. to Defs.' Motion for Summary Judgment on Preemption;
- Doc. #: 2179 – Plaintiffs' Opp. to Defs.' Motion for Summary Judge on Statute of Limitations; and
- Doc. #: 2203 – Plaintiffs' Opp. to Defs.' Motion for Summary Judgment on Causation.